

III. Claim 30; drawn to a composition that comprises the ingredients of Group II together with other specific compounds; and

IV. Claims 3, 5, 7, 9, 11, 12, 14, 16, 18, 19, 21, 23, and 32; drawn to a composition that requires the presence of alcohols.

Applicants hereby provisionally elect, with traverse, Group II, claims 2, 25, 27, 29, and 31, to prosecute in the above-identified patent application.

More specifically, Claim 30 is dependent on Claim 2. Applicants have amended Claim 30 herein to clarify this relationship. Therefore it would not require significant burden to search the claims of Group II with the claim of Group III. As such, Applicants respectfully request that Claim 30 be rejoined with Group II.

In addition, as the Examiner has noted, Groups I and II are not related as “product and process of use” nor as “product and process of making”. Indeed, the steps of Claim 1 reiterate the components of the formulation in Claim 2. Both of the claims also include functional language related to increase of viscosity. Applicants thus maintain that it would not require significant burden to search Groups I and II at the same time. Applicants respectfully request that Groups I and II be rejoined.

Finally, the dependency of Claim 4 has been amended herein such that it now depends on Claim 1 rather than Claim 1 or Claim 3. Applicants request that Claim 4 be joined with the claims of Group I.

The Office has also required election of species for prosecution on the merits to which the claims shall be restricted if no generic claim is held to be allowable. More specifically, elections of species of “hydrophobic active ingredient”; “polyglycerol ester”; and “specific mixture corresponding to part (d) of Claims 1, 2, or 3” are required.

Applicants provisionally elect, with traverse, the species of:
cyclosporin as the hydrophobic active ingredient;
polyglycerol-10-mono-oleate and polyglycerol-3-mono-oleate as the polyglycerol esters of component (b) and (c), respectively; and

macrogol(1760) glycerol hydrogenated castor oil as component (d).

These species are readable upon all claims of Groups I, II, and III, except Claims 26 and 27 which are drawn to formulations and methods having a taxane as the active ingredient.

A clean version of the amended claim with instructions for entry pursuant to 37 C.F.R. §1.121(c)(1)(i) is included above. A marked-up version of the amended claim pursuant to 37 C.F.R. §1.121(c)(1)(ii) is attached as Appendix I.

CONCLUSION

For the reasons presented above, the Applicants respectfully submit that the claims pending in the above-identified application are in condition for allowance. A Notice of Allowance is therefore respectfully requested.

Respectfully submitted,
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MARKED UP VERSION OF AMENDED CLAIMS

2. (Amended) A pharmaceutical formulation for oral or topical administration including

- a) an effective amount of one or more hydrophobic active ingredients;
- b) 5 to 50% of one or more compounds selected from polyglycerol esters of fatty acids of formula (1)



wherein n is an integer from 4 to 13 and R is H or $\text{CO}_2\text{R}'$ wherein R' is C_{8-22} saturated, unsaturated or hydroxylated alkyl and wherein at least one group R is not hydrogen;

- c) 5 to 50% of one or more compounds selected from polyglycerol esters of fatty acids and/or unsaturated fatty acids of formula (2)



wherein n is an integer from 0 –10 and $\text{R} = \text{H}$ or $\text{CO}_2\text{R}''$ wherein R'' is C_{8-22} saturated, unsaturated or hydroxylated alkyl, and wherein [while] at least one group R is not hydrogen;

- d) 5 to 50% of one or more compounds selected from the group consisting of triglyceride macrogol glycerol esters, partial glycerides [or] of fatty acids [or] and magrogol esters of fatty acids in which the average quantity of reacted ethylene oxide in the synthesis of these substances ranges between 50 to 150 mols and concurrently the ratio between components b) and d) is from 0.1:1 to 10:1;

wherein the above percentages are selected to total 100%;

and wherein upon dilution with water 1:1 by volume the viscosity of the formulation increases by at least 5 times in comparison to the undiluted composition.

4. (Amended) A method [or pharmaceutical formulation] as claimed in claim [3] 1, wherein the ratio of a:c [and/or a:e] is in the range 0.001 : 1 to 10 : 1.

30. (Amended) A formulation as claimed in [any] claim 2, wherein said formulation further comprises [further including] excipients to modify the physical, chemical, microbial stability, organoleptic or physical processing properties of the formulation.